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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,320	11/08/2001	Roman M. Barabolak	112703-211	2531

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EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,320	BARABOLAK ET AL.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 4-12-04.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-24 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election of Species Requirement

The election of species requirement is withdrawn.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 11, there is no antecedent basis for reciting "the emulsion" of claim 6.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1-5, 15, 19-21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/17159.

Hackh's Chemical Dictionary (4th Edition) provides the following definitions:

"Emulsion":

> A fluid consisting of a microscopically heterogenous mixture of 2 normally immiscible liquid phases, in which one liquid forms minute droplets suspended in the other liquid.

"Emulsifier":

> A substance that makes an emulsion more stable (as, ammonium lineolate), by reducing the surface tension or protecting the droplets with a film.

WO 95/17159 discloses antiplaque emulsions for mouthwashes comprising flavoring oils and the water-insoluble, non-cationic antimicrobial triclosan, the antimicrobial cationic surfactant cetylpyridinium chloride, and water. See the claims of the patent; page 12, lines 4-7; and page 13, lines 5-12. The prior art provides the following description at the passage spanning pages 3 and 4:

> Without being limited by theory, it is believed that before dilution, as the oil phase and aqueous phase mix, the flavoring oils which are highly water-insoluble become uniformly dispersed within the water phase of the ready-to-use mouthrinse. The water-insoluble, non-cationic antimicrobial of the present invention, combining with the flavor oils, is likewise dispersed throughout this phase. The cationic antimicrobials of the present invention, due to the inherent properties of both a hydrophobic and hydrophilic moiety, reside primarily at the oil-water interface. Specifically, the hydrophobic moieties of the cationic antimicrobial reside within the dispersed oily phase of the bi-phasic mixture whereas the charged, hydrophilic moieities of the cationic antimicrobial position themselves around the surface (or oil-water interface) of the oily droplets, forming countless micellar particles. It is the formation of this biphasic mixture and, in particular, the positioning of the cationic antimicrobial at the oil-in-water interface which contributes to the efficient antimicrobial delivery of the present invention.

This description by the prior makes clear that in the emulsions disclosed thereby, the surfactant cetylpyridinium choloride is simultaneously functioning as an emulsifier and surfactant. The instantly claimed compositions, which contain an emulsifier and a surfactant, are thus anticipated by the prior art disclosure, where cetylpyridinium chloride fulfills both roles.

The prior art thus meets each and every limitation of base claim 1, and of dependent claims 2, 15, 19 and 23 as well. It meets each and every limitation of the remaining dependent claims also, as follows:

I. Claims 3 and 20, three to thirty percent triclosan by weight of the emulsion, see page 10, line 5 of the prior art;

II. Claims 4 and 21, 0.1 to 10 weight percent surfactant by weight of the emulsion, see page 5, line 9 of the prior art; and

III. Claim 5, water and a solvent for the triclosan, see page 10, lines 10-32.

2) Claims 1, 3-5,15-18, 20, 21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Reed et al (USP 5,032,385).

The prior art discloses compositions containing triclosan (col. 1, last line; see also working example 1 at the bottom of col. 2), surfactant and water, which "partition into a hydrophilic phase and a surfactant micellar phase" (col. 1, lines 13-15), i.e. which are emulsions. (Note that "emulsifying agents" may also be added as disclosed at col. 2, lines 42 and 43). The triclosan may be present in an amount of up to two percent by weight (col. 1, line 37), which meets the limitation of "approximately" three percent in

claims 3 and 20 since that term permits some flexibility. The surfactant may be present in an amount of 0.1 to 10 weight percent as required by instant claim 4 (see col. 4, lines 11-16). Water and solvents (flavor oils) are included as well; see col. 1, lines 17-19 and working example 1 at the top of col. 3, for example. The prior art composition may be present as a chewing gum as required by instant claim 16 (col. 2, line 52), and as a toothpaste as required by instant claim 24 (col. 2, line 61).

Instant claims 17 and 18 recite that the chewing gum "is chewed" for at least five minutes (claim 16), or at least three times per day. One would expect these limitations to be inherent, or able to be "immediately envisaged", in any disclosure of a therapeutic chewing gum. Additionally, it is noted that the claim construction attempts to introduce a transient process limitation, comprising a moment in time, into a product claim. As a practical matter, such a recitation cannot serve as a positive limitation; at best, "is chewed" functions only as a statement of intended use. By this interpretation, the limitation carries no patentable weight, so the claims are likewise anticipated.

3) Claims 1, 6-8, 12-18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Hill (USP 5,380,530).

The prior art discloses antiplaque chewing gums comprising a water insoluble chewing gum base portion and a water soluble therapeutic portion, the latter containing an emulsion coating which may contain therapeutic agents such as triclosan. See col. 9, lines 30-37; col. 13, lines 54-59; and col. 15, lines 12-25. Flavoring oils (which are solvents for triclosan) are included (see col. 17, lines 23-34; note the use of peppermint

oil in working example 1 at col. 21 as well). The water-insoluble chewing gum base portion may be in stick or pellet form: see col. 18, lines 12-24 (bubble gum generally comprises pellets). Example 17 in Table II (see cols. 15 and 16) describes chewing gums comprising an emulsion coating comprising 1 percent by weight Triclosan, a surfactant and a polydimethylsiloxane (referring back to Table 1, spanning cols. 11 and 12). Where the chewing gum weighed 100 mg, as disclosed at col. 12, line 43, this gum would contain 1 mg triclosan, meeting the limitations of instant claims 12 and 22.

The prior art does not specifically disclose a preferred embodiment or working example containing a composition comprising triclosan, a surfacant and an emulsifier. It does, however, specifically and unambiguously teach that surfactants and emulsifiers may be used in combination. See for example col. 13, line 49. This means that to arrive at the emulsions of the instantly rejected claims, which require no particular percentage of surfactant or emulsifier, one must merely choose from just three limited and related possibilities – one where a surfactant only is present (present in the preferred embodiments and working examples), one where a mixture of surfactant and emulsifier is present, and one where an emulsifier only is present. Since this choice is so limited, the prior art is seen to anticipate the instantly claimed subject matter.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 15 and 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al (USP 5,032,385).

The prior art is discussed in detail in subsection "2)" of the "Anticipation" section above, and differs from instant claim 22 insofar as, although it teaches chewing gums at col. 2, line 52, it does not specifically disclose the amount of active ingredient, i.e. 1 to 6

mg triclosan as required instantly. (Claim 15 is included herein insofar as claim 22 depends therefrom.)

It is well-settled that changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find *workable* conditions generally involves no more than the application of routine skill in the art. *In re Aller* 105 U.S.P.Q. 233. Consonant with this reasoning, since dosage is a "result effective variable" which depends on degree (i.e. the magnitude of the dose), it would have been obvious to have experimented to find workable dosages for the chewing gums of the prior art, using no more than routine experimentation. Stated alternatively, it would have been obvious to the skilled artisan to have ascertained useful dosage ranges, motivated by the desire to optimize therapeutic performance.

2) Claims 6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill (USP 5,380,530) in view of WO 95/17159.

The primary reference is discussed in subsection "3)" of the "Anticipation" section above and differs from instant claims 9-11 (claim 6 is included since they depend therefrom) insofar as it does not emulsion coatings i) comprising cetylpyridinium chloride in combination with triclosan, ii) comprising 3 to 30 percent triclosan, or iii) 0.1 to 10 weight percent surfactant. Regarding i), it is noted that although the prior art does mention cetylpyridinium chloride at col. 15, line 30, it must be selected from a moderately large list of widely varied antimicrobial agents. To select it from this group, and then to further select a mixture of same with triclosan, would require too much

"picking and choosing" to support a finding of anticipation. Regarding ii), the only specific amount of triclosan disclosed in the prior art is 0.2 to 1 percent by weight in the table spanning cols. 15 and 16. Finally, regarding iii), the only specifically disclosed proportions of surfactant in the prior art are higher than 10 percent (see the passage spanning cols. 11 and 12, and working example 1 at col. 21).

The secondary reference is discussed in detail in subsection "1)" of the "Anticipation" section above, and differs from the instant claims since it is silent regarding chewing gums. It does teach, however, that the particular combination of triclosan and cetylpyridinium chloride in emulsion form, in amounts within the instantly claimed ranges, provides improved delivery of those antiplaque agents. See for example page 2, lines 6-20.

A stated goal of the inventors of the primary reference is to improve delivery of therapeutic agents such as triclosan. See for example col. 9, lines 49-69. The secondary reference explicitly teaches that a mixture of triclosan and cetylpyridinium chloride, in emulsion form, provides improved delivery of those therapeutic agents. Accordingly, it would have been obvious to have used a mixture of triclosan and cetylpyridinium chloride as a therapeutic agent in the emulsions of the primary reference, motivated by the desire to provide improved delivery as taught by the secondary reference.

Obviousness-Type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,436,369, taken in view of Hill (USP 5,380,530). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are clearly drawn to coextensive subject matter.

The instant claims are drawn to triclosan emulsions and chewing gums containing them. They are generic to the conflicting claims, which specifically recite chewing gums in pellet form, with a water-insoluble and water-insoluble portion, and containing 1 to 6 mg triclosan, and methods for using such chewing gums to reduce plaque. The instant claims thus recite some of the features of the conflicting claims (e.g. 1 to 6 mg in instant claims 12 and 22), but not all simultaneously.

It is well-known in the art to prepare therapeutic chewing gums in pellet form, with the therapeutic agent being present on a water-soluble emulsion coated thereupon. See Hill at col. 18, lines 10-24 (bubble gum is in pellet form) and col. 15, lines 12-30, for example. One percent triclosan (see example 17 at Table II spanning cols. 15 and 16), when included in a 100 mg coating per piece of gum (col. 12, line 43), would provide at least 1mg of active ingredient.

Accordingly, it would have been obvious to have prepared, from a composition of the instant claims, a chewing gum having all the specific features recited by the conflicting claims, since they are merely standard forms of same as illustrated by Hill.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 6:30-3:00PM;
Tuesday: 10-6:30PM;
Wednesday: off;
Thursday: 10-6:30PM; and
Friday: 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614